

4354-110

RECEIVED  
CENTRAL FAX CENTER  
JUL 01 2009

**Section I (Amendments to the Claims)**

Please amend claims 2-5 as set out in the following listing of the claims of the application.

1. (Original) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 5 mg.
2. (Previously Presented) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 3 mg.
3. (Previously Presented) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 1 mg.
4. (Previously Presented)-A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.2 and 0.8 mg.
5. (Currently Amended) The pharmaceutical composition of any of claims 1 through 4 3, wherein said unit dosage is a tablet, pill, capsule, or caplet.
- 6-43. Cancelled.
44. (Withdrawn) A method for treating an infection of a bacterium having a multiplying form and a non-multiplying form, said method comprising administering to a patient (i) rifalazil; and (ii) a second antibiotic effective against the multiplying form of said bacterium, wherein said rifalazil is administered in an amount and for a duration effective to treat the non-multiplying form of said bacterium and the second antibiotic is administered in an amount and for a duration effective to treat said multiplying form of said bacterium and wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil.
45. (Withdrawn) The method of claim 44, wherein said antibiotic effective against said multiplying form of said bacterium is administered to said patient in an amount and for a duration to reduce the presence of said bacterium in said patient to less than about  $10^6$  organisms/mL; and rifalazil is then administered to said patient in an amount and for a duration

4354-110

effective to reduce the presence of said bacterium to or below a level indicative that said infection has been treated.

46. (Withdrawn) A method of eradicating non-multiplying bacteria not eradicated in a patient following treatment with a first antibiotic, said method comprising administering rifalazil to said patient in an amount and for a duration effective to eradicate said non-multiplying bacteria in said patient, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil.

47. (Withdrawn) A method of treating a patient diagnosed as having a chronic disease associated with a bacterial infection caused by bacteria capable of establishing a non-multiplying form phase, said method comprising administering rifalazil to said patient in an amount and for a duration effective to treat said patient, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil.

48. (Withdrawn) A method of treating the cryptic phase of a bacterial infection, said method comprising administering rifalazil to said patient in an amount and for a duration effective to treat said cryptic phase of said bacterial infection, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil.

49. (Currently Amended) A pharmaceutical formulation comprising rifalazil, wherein said formulation is packaged with a label or package insert providing instructions for the use of said formulation, said instructions describing administration of said rifalazil using a loading-dose regimen.

wherein said formulation is provided in a prepackaged therapeutic regimen comprising: a first dosage unit comprising rifalazil; a second dosage unit comprising a smaller dose of rifalazil than said first dosage unit; instructions for the administration of said first dosage unit prior to said second dosage unit; and a pharmaceutical dispensing container prefilled with said dosage units and incorporating said instructions, and

wherein said second dosage unit comprises between 0.1 and 5.0 mg of rifalazil.

50-51. (Cancelled)

4354-110

52. (New) The pharmaceutical composition of claim 3, wherein said unit dosage is a tablet, pill, capsule, or caplet.

53. (New) A composition comprising

a) rifalazil, in unit dosage form, wherein each dose is in the range of between 0.1 and 5 mg, and

b) instructions for administration on a daily basis for a period of time of at least two consecutive days.

54. (New) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 5 days.

55. (New) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 10 days.

56. (New) The composition of Claim 53, wherein the instructions are for daily administration for a period of at least 30 days.

57. (New) The composition of Claim 53, wherein the instructions are for daily administration for a period of 4 to 14 days.

58. (New) The composition of Claim 53, wherein the instructions are for daily administration for a period of 4 to 10 days.

59. (New) The composition of any of Claims 53-58, wherein the dosage is between 0.1 and 3 mg.

60. (New) The composition of any of Claims 53-58, wherein the dosage is between 0.1 and 1 mg.